FDA DOCUMENTATION FOR THE GENERIC CLEARANCE FOR THE COLLECTION OF QUALITATIVE DATA ON TOBACCO PRODUCTS AND COMMUNICATIONS (0910-0796)

TITLE OF INFORMATION COLLECTION: Qualitative Study of Perceptions and Knowledge of Visually Depicted Health Conditions

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**
   The Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) is seeking OMB approval under generic clearance 0910-0674 to conduct in-depth interviews (*n*=54) with youth ages 12-17 who are susceptible to smoking, young adult smokers ages 18-24, and adult smokers ages 25-60. The research will be fielded to assess participants' understanding of cigarette graphic health warning (GHW) images designed to increase knowledge and correct misperceptions about the negative health consequences of cigarette smoking.

2. **Intended use of information:**
   Information obtained through this study will inform the development of new cigarette GHW labels designed to increase knowledge and correct misperceptions of the negative health consequences of cigarette smoking. Study participants will view draft images depicting a range of negative health consequences and answer questions regarding image comprehension, relevance, and believability. The results will be used to identify the most promising images as well as indicate areas for further refinement.

3. **Description of respondents:**
   The study will consist of fifty-four (54) participants, including eighteen (18) non-smoking youth ages 12-17 who are open to smoking, eighteen (18) young adult smokers ages 18-24, and eighteen (18) adult smokers ages 25 to 60. Eighteen (18) of the fifty-four (54) participants will be Spanish-reading. Study participants will be otherwise diverse in race/ethnicity and gender. Up to one thousand (1,300) potential participants will be screened to obtain the desired sample size of fifty-four (54) total participants.

4. **Date(s) to be conducted:**
   Data collection is projected to occur two (2) weeks after final OMB approval is received, and will last for approximately four (4) months.

5. **How the information is being collected:**
   The information will be collected through fifty-four (54) in-depth interviews led by either an English- or Spanish-speaking professional interviewer in private meeting rooms or research facilities. The interviewer will ask each participant a series of questions using a semi-structured interview guide and encourage participants to respond openly and spontaneously. Each interview will last up to sixty (60) minutes. Individual interviews with English-speaking participants will be live streamed to allow FDA staff to remotely monitor the sessions. All interviews will be audio-recorded to aid in data analysis.

   <u>GHW Image In-Depth Interviews: 60 minutes</u>

   After the participant check-in process (5 min.) is completed, the interviewer will obtain the participant's consent for audio recording and live streaming, read a brief statement describing the research purpose and the interview process, and ask the participant a few introductory questions (10 min.). The participant will then be shown up to twelve (12) draft

images depicting negative health consequences of cigarette smoking in random order. After each image is shown, the interviewer will ask the participant a series of questions to obtain feedback on image comprehension, relevance, and believability (35 min.). At the conclusion of the interview, the participant will be asked to briefly review twelve (12) additional images at the same time for comparison and feedback (5 min.). Finally, the interviewer will end the interview and assist the participant with collecting his or her incentive (5 min.).

6. Confidentiality of respondents:

All data will be collected with an assurance that the participant's responses will remain private to the extent allowable by law.

Researchers will inform participants in the consent form that the information they provide in the screener for recruitment will only be viewed by the researchers. Additionally, interview questions will not ask participants to provide identifying information as part of their responses, and no identifying information will be included in the data files delivered by contractors to the agency.

Identifying information will not be included in the report delivered to the agency. All data received by the FDA will remain in a secured area or on a password-protected computer. No transcripts or analysis will contain identifying information.

Neither the contractor nor subcontractors associated with this study will share personal information regarding research participants with any third party without the participants' permission, unless it is required by law to protect their rights or to comply with judicial proceedings, a court order, or another legal process.

7. Amount and justification for any proposed incentive:

The amount of the incentive as a token of appreciation is $75 for adult participants, $40 for youth participants, and $25 for the parents of youth participants who bring them to the interviews. The incentives will be in the form of a gift card. FDA will be asking respondents to provide thought-intensive, open-ended feedback on concept images that require a high level of engagement. Additionally, FDA requires participation from specialized populations that meet specific criteria including English speaking/reading youth who are susceptible to smoking (less than 30% of the youth population), English speaking/reading current young adult and adult smokers (less than 18% of the adult population), Spanish primary language speaking/reading smoking youth who are susceptible to smoking and/or who smoke, and Spanish primary language speaking/reading young adult and adult smokers. Based on feedback from local research facilities, low incentive rates can cause difficulties in recruiting participants from these subsets, resulting in an insufficient number of participants to successfully complete this study. Low incentive rates can also impact the ability to procure a suitable research facility as some facilities have declined to participate in prior studies due to insufficient incentives for recruitment.

To determine the appropriate incentive amount for the participants in this study, FDA spoke directly to the research facilities the Agency intends to hire for this research. Based on the significant past experience of both facilities, incentive rates have clearly influenced cancellations and no show rates. On several occasions this has required the facilities to over-recruit well above the normal rate to ensure a sufficient number of completed interviews. As a result, the overall project costs were increased due to recruiting more respondents to compensate for the lower incentive.

The facilities noted they consider the research topic particularly sensitive, especially in terms of asking underage children about smoking, and stated that young adults are often the least reliable audience subset to recruit for research. The facilities also noted that in addition to parents having to provide their child transportation to the facility, they may need to factor in babysitters for other children as well. Adult participants with children may also need to pay for childcare and transportation in order to participate.

One facility recently conducted a test to measure the impact of incentive amount on recruitment and interview completion success. With a $50 incentive, the facility was only able to recruit 15 respondents and complete 9 interviews. After increasing the incentive to $75 they recruited 18 respondents and completed 17 interviews.

The facility explained that while respondents may commit to the study initially, if traffic ends up being bad, or some other potential barrier to attending emerges, the participant will forego participating altogether if the cost of attending exceeds the incentive. This issue is especially more likely for the Spanish speaking audience, as they are more likely to live further away from the research facility. As a result, past clients attempting to use a lower incentive have ended up having to increase the incentive in order to complete the number of interviews, extending both total costs and timelines.

When taking into account the difficulty of the recruit, travel time, length of the interviews, and prior incentive amounts and show rates, both facilities recommend incentives higher than what FDA is proposing, in some cases twice as much. If we maintain the rate we have proposed, or go even lower, the facilities noted we risk having a lower response rate and higher number of no shows.

Questions of a sensitive nature:

Some studies require the inclusion of people who match selected characteristics of the target audience that the FDA is trying to reach. This may require asking questions about race/ethnicity, income, education, and health behaviors on the initial screening questionnaire used for recruiting. Potential participants are informed that this is being done to make sure that the FDA speaks with the kinds of people for whom its messages are intended. Respondents are assured that the information is voluntary and will be treated as private to the extent allowable by law. All information on race/ethnicity will fully comply with the standards of OMB Statistical Policy Directive No. 15, October 1997 (http://www.whitehouse.gov/omb/fedreg/1997standards.html).

FDA tobacco use communications may be concerned with the prevention of premature mortality from heart disease and oral and respiratory cancers, and some projects may involve asking questions about (or discussing) how one perceives his or her own personal risk for serious illness. This information is needed to gain a better understanding of the target audience so that the messages, strategies, and materials designed will be appropriate and sensitive. Questions of this nature require some sensitivity in how they are worded and approached. Participants are informed prior to actual participation about the nature of the activity and the voluntary nature of their participation.

Raw data that include sensitive information (e.g., screening questionnaires) are not retained once the data have been extracted and aggregated. The information never becomes part of a system of records containing permanent identifiers that can be used for retrieval.

8. Description of statistical methods:

This research relies on qualitative methods to collect data. This research is not intended to yield results that are statistically projectable, nationally representative, or precise estimates of population parameters.

BURDEN HOUR COMPUTATION *Number of respondents (X) estimated response or participation time in minutes (/60) = annual burden hours:*

Type / Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screened Potential Participants			
Screening Questionnaire			
Adult	700	5	58
Youth	300	5	25
Parent	300	5	25
Consent			
Consent (36 Adults & 18 Parents)	54	5	4.5
Assent (18 Youth)	18	5	1.5
Subtotal			**114**
Interview Participants			
Interview Discussion	54	60	54
Total			**168**

REQUESTED APPROVAL DATE: 9/18/2015

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FDA CENTER: Center for Tobacco Products (FDA/CTP)